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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,615	08/22/2003	William J. Hennen	2820-5474.1US	8609

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EXAMINER	
KIM, TAEYOON	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/646,615	HENNEN, WILLIAM J.	
	Examiner	Art Unit	
	Taeyoon Kim	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-67* is/are pending in the application.

4a) Of the above claim(s) *19-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 50-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/25/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-67 are pending.

Election/Restrictions

1. Applicant's election without traverse of Group I invention in the reply filed on July 31, 2006 is acknowledged. In response to the species election requirement, Applicant has elected the following species.

Type of microorganisms: HSV-II

Type of antioxidants: vitamin E

Claims 19-49 are withdrawn from consideration as being drawn to non-elected subject matter. Claims 1-18 and 50-67 have been considered on the merits.

Specification

2. The disclosure is objected to because of the following informalities: In page 6, paragraph 6, "U.S. Patent 5,650,148 to Rath et al." is disclosed. The patent number is incorrect. It should be 5,650,418.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-3, 7, 8, 10-15,17, 50-52, 56, 57, 59-64 and 66 are rejected under 35 U.S.C. 102(e) as being anticipated by Ramaekers (U.S. Patent 6,506,413 B1; filed on Apr. 30, 2001).

Claims 1-3, 7, 8, 10-15, 50-52, 56, 57 and 59-64 are drawn to a composition for treating cardiovascular disorders comprising an inflammation-reducing component for decreasing inflammation in blood vessels comprising transfer factor (claims 1 and 2), or a pathogen-reducing component for decreasing pathogens in blood vessels comprising transfer factor (claims 50 and 51), with a blood flow-enhancing component; limitations to the transfer facto of claims 2 and 51 being antigen-specific or pathogen-specific (claims 3 and 52); being mammalian transfer factor (claims 7 and 56); the mammalian transfer factor comprising a colostrums extract (claims 8 and 57); the composition of claim 1 or claim 50 comprising an LDL receptor-binding component (claims 10 and 59); the LDL receptor-binding component comprising lysine or lysine salt (claims 11 and 60); the blood flow-enhancing component comprising arginine or nicotinamide (claims 12 and 61); the composition of claim 1 or claim 50 further comprising antioxidant (claims 13 and 62); the antioxidant being hydrophobic (claims 14 and 63); the hydrophobic antioxidant being vitamin E (claims 15 and 64); the composition further comprising a cholesterol-reducing element (claims 17 and 66); and the composition further comprising a fat oxidation prevention element (claims 18 and 67).

Ramaekers teaches a composition containing mammalian transfer factor which would be antigen-specific (varicella antigen; column 1, lines 29-30) or pathogen-specific

(herpes simplex virus; column 1, lines 21-22) (claims 1-3, 7, 50-52 and 56) from colostrums extract (claims 8 an 57), arginine or nicotinamide (niacinimide) (claims 12 and 61), lysine (claims 10, 11, 59 and 60), a hydrophobic antioxidant as well as a fat oxidation prevention element, vitamin E (claims 13-15, 18, 62-64 and 67) (see column 2; table 2), niacin, a cholesterol-reducing element supported by (see column 2, line 65).

Although Ramaekers do not specifically teach that lysine as a LDL receptor-binding component (claims 11 and 60), arginine being a blood flow-enhancing component (claim 10 and 59), niacin being a cholesterol-reducing element (claims 17 and 66), or vitamin E, a fat oxidation prevention element (claims 18 and 67), it is an inherent property of lysine/lysine salt, arginine, or niacin having a property as a LDL receptor-binding component, a blood flow-enhancing component, or cholesterol-reducing element as supported by Rath et al. (U.S. Patent 5,650,418), Tentolouris et al. (Int. J. Cardiol., 2000,75(2-3):123-128), Cholesterol-lowering drugs (http://www.americanheart.org/presenter.jhtml?identifier=4510; page 2), or Focant et al. (J. Dairy Sci. 1998, 81:1095-1101, Abstract), respectively.

Although Ramaekers does not specifically teach the intended use of the composition for cardiovascular disorders, the composition of Ramaekers containing an inflammation-reducing component such as transfer factor, a blood flow enhancing component such as arginine and niacinimide, and a LDL receptor-binding agent such as lysine salt would inherently possess an ability to treat cardiovascular disorders as supported by Gordon (Explore, 1999, http://www.explorepub.com/articles/heart_disease.html, page 3), Kirkpatrick (J. Allergy

and Clin. Immunol. 1975, 55(6):411-421; Abstract) and Tentolouris et al. (supra; Abstract), respectively.

Thus, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 4-6, 9, 16-18, 53-55, 58 and 65-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramaekers (supra) in view of Tokoro (U.S. Patent 5,080,895; published on Jan. 14, 1992) or Hennen et al. (U.S. Patent 6,468,534 B1).

Claims 4-6 and 53-55 are drawn to limitations to the composition of claims 1 or 50 being nonmammalian (claims 4 and 53); being avian transfer factor (claims 5 and 54); the avian transfer factor comprising an egg extract (claims 6 and 55).

Ramaekers teaches a composition having transfer factor and arginine and/or nicotinamide (claims 1 and 2).

Ramaekers does not teach that the transfer factor is non-mammalian, avian nor from egg extract.

Tokoro teaches transfer factor from egg extract of immunized hen (see Examples).

Hennen et al. also teach non-mammalian transfer factor from immunized hen (see Abstract).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to replace the mammalian transfer factor of Ramaekers with the transfer factor from egg extract taught by Toroko.

The skilled artisan would have been motivated to make such a modification because the production of transfer factor (food factor) in a large amount from colostrums is difficult and limited due to its production is limited to a few days, and furthermore necessitates a vast farm land according to Toroko (see column 1, lines 39-49).

The person of ordinary skill in the art would have had a reasonable expectation of success in replacing transfer factor of Ramaekers with that of Toroko because the production of transfer factor and/or antibody from eggs of immunized hen has been successfully practiced in the art.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

5. Claims 9 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramaekers (supra) in view of Kirkpatrick et al. (U.S. Patent 5,470,835; published on Nov. 28, 1995) in further view of Vercellotti (Trans. Am. Clin. Climatol. Assoc. 2001, 112:215-222; Abstract).

Claims 9 and 58 are drawn to limitations to an inflammation-reducing component or a pathogen-reducing component in the composition of claim 1 or 50 being specific for HSV-II (claims 9 and 58).

Ramaekers teaches a composition having transfer factor as an inflammation-reducing component (claim 1) or a pathogen-reducing component (claim 50), and arginine and/or nicotinamide as a blood flow-enhancing component.

Ramaekers also teaches transfer factor is an effective therapeutic for Herpes simplex virus (HSV) (column 1, lines 21-22).

Ramaekers does not teach transfer factor being specific for HSV-II.

Kirkpatrick et al. teach transfer factor specific for HSV-II.

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to use transfer factor specific for HSV-II of Kirkpatrick et al. in the composition of Ramaekers.

The skilled artisan would have been motivated to make such a modification because since Vercellotti teaches that HSV-II infected individuals have the greatest relative risk for coronary artery disease (see Abstract), transfer factor specific for HSV-II would reduce the risk factor for coronary artery disease in human, hence even more beneficial in treating cardiovascular disorders.

The person of ordinary skill in the art would have had a reasonable expectation of success in using transfer factor specific for HSV-II in the composition of Ramaekers to treat cardiovascular disorders because transfer factor specific for HSV-II has been successfully generated by Ramaekers.

6. Claims 16 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramaekers (supra) in view of Singh et al. (J. Assoc. Physicians India, 1998 46(3):299-306; Abstract).

Claims 16 and 65 are drawn to limitations to the antioxidant comprising coenzyme Q10 (claims 16 and 65).

Although Ramaekers does not teach the use of coenzyme Q10 in the composition, it would have been obvious for the person of ordinary skill in the art at the time the invention was made to replace antioxidants such as vitamin E taught by Ramaekers with coenzyme Q10, another well-known antioxidant taught by Singh et al., for the same purpose.

Furthermore, the skilled artisan would have been motivated to make such a modification because Singh et al. teach Coenzyme Q10 deficiency in patients with congestive heart failure and coronary artery disease (see Abstract) and therefore providing a motivation to replace vitamin E with coenzyme Q10 which would be beneficial to cardiovascular disorders.

M.P.E.P. § 2144.06 states "*In re* Ruff, 256 F.2d 590, 118 USPQ 340 (CCPA 1958) (The mere fact that components are claimed as members of a Markush group cannot be relied upon to establish the equivalency of these components. However, an applicant's expressed recognition of an art-recognized or obvious equivalent may be used to refute an argument that such equivalency does not exist.); *In re* Scott, 323 F.2d 1016, 139 USPQ 297 (CCPA 1963) (Claims were drawn to a hollow fiberglass shaft for archery and a process for the production thereof where the shaft differed from the prior

art in the use of a paper tube as the core of the shaft as compared with the light wood or hardened foamed resin core of the prior art. The Board found the claimed invention would have been obvious, reasoning that the prior art foam core is the functional and mechanical equivalent of the claimed paper core. The court reversed, holding that components which are functionally or mechanically equivalent are not necessarily obvious in view of one another, and in this case, the use of a light wood or hardened foam resin core does not fairly suggest the use of a paper core.); Smith v. Hayashi, 209 USPQ 754 (Bd. of Pat. Inter. 1980) (The mere fact that phthalocyanine and selenium function as equivalent photoconductors in the claimed environment was not sufficient to establish that one would have been obvious over the other. However, there was evidence that both phthalocyanine and selenium were known photoconductors in the art of electrophotography. "This, in our view, presents strong evidence of obviousness in substituting one for the other in an electrophotographic environment as a photoconductor." 209 USPQ at 759.). An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. In re Fout, 675 F.2d 297, 213 USPQ 532 (CCPA 1982)."

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 8:00 am - 4:30 pm ET (Mon-Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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